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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/981,248	HOFFMAN ET AL.	
	Examiner	Art Unit	
	JASON SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *85-89,91-94,96-100,103 and 104* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *85-89, 91-94, 96-100, and 103-104* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 8/18/2011, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 8/18/2011, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claim 104 in the response filed 8/18/2011, which is acknowledged and entered.

Applicant has cancelled claims 101-102 in the response filed 8/18/2011.

Claims 85-89, 91-94, 96-100, and 103-104 are the current claims hereby under examination.

Claim Objections

The objections to claims 85 and 103 are being withdrawn because of applicant's amendments.

Claim Rejections - 35 USC § 112-First Paragraph

Response to Arguments

Applicant's arguments, filed 8/18/2011, with respect to the rejection of claims under 35 USC 112 first paragraph have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejections have been withdrawn.

Claim Rejections - 35 USC § 112-Second Paragraph

Response to Arguments

Applicant's arguments, filed 8/18/2011, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's cancellation of claims 101-102. Therefore the rejections have been withdrawn.

The following rejections have been maintained/modified which were necessitated by amendment:

Claim Rejections - 35 USC § 103-Maintained/Modified

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 85-89, 91-94, 96-100, and 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000) and further in view of Fey et al. (US Pub. 2002/0038227, filed 2/26/01), further in view of Hogan (US A/N

2002/0110823), in view of Bowie (US P/N 5,750,345) and further in view of Levine et al. (US P/N 2003/0011646).

Claims 85, 91, and 94 are directed to a computer-implemented method and/or computer program implementing instructions for processing hereditary data, and to a computer system and medium comprising instructions or components for performing the method, wherein the method comprises receiving a genetic test result value for a person, querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents, and outputting an "interpretation" of the genetic test result value and the list of risk-associated agents. Claim 55 comprises amended further limitations directed towards automatically obtaining genetic test result values and further limitations towards a process for obtaining a genetic test result value. Claim 85 comprises amended further limitations directed to displaying notification windows in the GUI, comprising likelihoods of a patient having the genetic variabilities. Claims 26, 56, 86 and 91 further limit the method to comprise determining if a patient has been exposed to a risk-associated agent. Claims 57 and 87 limit the method to further comprise accessing an electronic medical record. Claims 59-60 and 89-90 limit the method to comprise initiating a clinical action if a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent. Claim 93 limits the method to comprise determining whether to authorize in accordance with cost of the genetic test, a likelihood of a genetic variation based on demographic

information of the patient and either automatically or through the physician ordering the genetic test.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathioprine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). ICHIKAWA does not specifically teach querying a computerized table listing polymorphism values and atypical events associated with the polymorphism values, electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with "idiosyncratic" drug reactions or altered drug sensitivity (p. 489, Table 1), thus teaching a list of "risk-associated agents". EVANS teaches that his Table 1 is a computerized table of atypical clinical events associated with polymorphism values (see the legend for Table 1 which states "A comprehensive listing is available at www.sciencemag.org/feature/data/104449.shl"). It is noted that Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught

by ICHIKAWA. It is further noted that the table of EVANS contains many of the genes, polymorphic sites, and atypical events disclosed by the instant specification in Table 2 on page 16. EVANS also teaches automated systems to associate an individual's genotype with polymorphic genes in order to optimize drug administration and disease treatment (p. 490, right column). EVANS does not specifically teach accessing an electronic medical record.

REINHOFF teaches a computer-implemented method, and a system and computer-readable medium comprising instructions for performing the method, wherein information with regard to a patient's polymorphic profile is linked to a degree of response of the patient to a treatment, specifically to side effects; i.e. an "atypical" clinical response (paragraphs 33, 38, 57 and 59). Specifically, REINHOFF teaches populating a computerized database with genotypic and phenotypic data (para 38) and teaches that polymorphic profiles of individuals may be associated with response to drugs in a computerized method (para 57). He further teaches analysis of such data in a computerized database (para 58), thus teaching a step of "querying" a computerized listing comprising polymorphic data and atypical clinical events associated with the polymorphic data. REINHOFF also teaches that a variety of electronic medical and/or clinical records may be accessed in his method (paragraph 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by REINHOFF, and to have accessed/queried a computerized list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA

and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59) and/or to determine an appropriate dosage of the agent, as taught by REINHOFF (paragraph 57) and ICHIKAWA (p. 523, left column, last paragraph).

REINHOFF suggests, but does not explicitly recite a graphical user interface having specific functionality.

REINHOFF suggests this because REINHOFF teaches, at paragraph [0040] computers running customized software supporting the service provided by the taught invention, wherein it is common for software to have built in GUIs for easier functionality for a user. Furthermore, REINHOFF teaches at paragraph [0010] that the computer program product allows identification of a susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain disease, i.e. it is commonly understood wherein a doctor would perform the risk assessment thereby implying that the networked system comprising the program product is intended not just for patients, but also doctors or hospitals.

Fey et al. teach at paragraphs [0022] [0048] and [0055] an application of health data management which involves a graphical user interface written for web browser applications wherein the user has a unique identification and may enter information through the GUI. Fey et al. at paragraph [0012] teach keeping secure health records, which are accessible by authorized health persons. Fey et al. further teach that custom reports are generated at the time tests are performed that explains the results. Fey et

al. teach at paragraph [0022] wherein results are prepared for the individual and physician. Fey et al. teach at paragraph [0047] wherein the health data may be used by doctors. In addition, Fey et al. at paragraphs [0053] – [0059] and [0063] – [0075] teach a system comprising a means, i.e. a displaying component and computer storage media configured for displaying a graphical user interface as in claims 55 and 85. With further regards to claim 85, Fey et al. teach at paragraph [0031] storing the genetic test results.

Fey et al. does not explicitly teach a GUI that is configured to solicit input from a clinician to ascertain whether to authorize performing a genetic test on a patient. In fact, Fey et al. teach, i.e. paragraph [0057] that the invention is directed to enabling a client/consumer to order genetic testing without doctor's approval. Furthermore, Fey et al. teach that a client can use the taught invention to determine genetic risk towards disease or conditions or discover genetic predispositions.

Although it appears that the invention of Fey et al. does not actually teach a physician based system, it is the functionality of said system, which is taught that is the focus. The invention taught by Fey et al. has the functionality of using a graphical user interface to solicit input, albeit a client, to ascertain whether to perform a genetic test, displays identification of the genetic test to be performed, receives approval or authorization from the client to carry out the genetic test, ensures identification of the person, and is configured to receive result value of the genetic test for the person.

Hogan at the abstract discusses a method for tailoring a subject's surgical treatment to reflect genetic information. Hogan at paragraph [0005] discusses that the choice of anesthetic regimen, agent, and dose depends on the type of surgery or

procedure. Hogan at paragraphs [0011] – [0013] discusses genomic screening of a subject prior or during a surgical procedure to obtain a genomic profile. Hogan at paragraphs [0019] – [0022] discusses obtaining a genomic profile for a subject which screens the subject for one or more polymorphism values associated with one or more clinical events associated with one or more clinical agents. Hogan at paragraphs [0018] and [0019] discusses screening a patient to determine a risk for surgical complications associated with known genetic variations. Hogan teaches at paragraph [0187] and Fig. 1, automated processes for obtaining a genetic test result value. Hogan teaches at paragraphs [0032] – [0038] and [0187] analyzing the cost-benefit of genomic profiling, which further reads on amended limitations of claim 55. Furthermore, Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor, which reads on displaying to the clinician a list of risk-associated agents, a warning of the effects of the polymorphism value, and alternate clinical agents that are not associated with the polymorphism value.

Additionally, Hogan at paragraph [0187] they teach a set of criteria to be met prior to administering a genetic test or genomic profile test, such as whether the subject is a candidate for genomic profiling, if a particular method is available for performing said test, if the method will provide useful information for a particular application and its practicality, and if there is clinical utility, i.e. provide a predication of a phenotype related to the genotype. Hogan at paragraphs [0005], [0008], and [0138] discusses assessing the dosages associated with the clinical agents and risk assessments. Hogan at paragraphs [0186] and [0188] – [0193] discusses that the clinical agent and genetic

information may be stored and communicated via various computerized applications, including electronic medical records including computers. Hogan at paragraph [0031] – [0033] discusses a problem is "how to alter treatment course of action in response to results," as in genomic screening results and the present invention unites "medicine with genetics" to solve the described problem and to individualize treatment options for each subject. Hogan at paragraphs [0190] – [0191] teaches outputting information about the atypical clinical event associated with the polymorphism values such that a "clinical action" may be initiated. Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor. Furthermore, Hogan at paragraphs [0115], [0129], [0136] – [0147], and [0186] teaches comparing genetic test result values for multiple genes to polymorphoism values associated with adverse reactions, i.e. risks associated with atypical clinical events, and that agent information may include dosage and other PK/PD parameters.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the system for authorizing genetic tests and displaying results, etc. as taught by Fey et al. and Hogan for use by a physician as taught by REINHOFF, ICHIKAWA and EVANS. This is because REINHOFF teaches a program product for studying genetic data and using genetic screening methods to assess increased risk of certain diseases and conduct basic research on population genetics. It would have been obvious to the skilled artisan to improve the invention of REINHOFF by adding a secured health data management system, wherein a physician can ascertain whether to authorize performing a genetic test on a patient based on their

assessed risk for a certain disease. REINHOFF teaches at paragraphs [0008] – [0009] using a web system to create polymorphic profiles for individuals. Therefore, creating a secured health data management system wherein the polymorphic profiles are stored and further genetic tests can be authorized as deemed necessary can be seen as an improvement wherein the results would be predictable. Moreover, a skilled artisan would find that the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

The combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN do not explicitly teach the limitation of the specific decision tree wherein when demographic information is inaccessible perform the step of utilizing genetic variability of a general population for calculating a second likelihood that the person displays genetic variability linked with genes associated with the genetic test.

Bowie teach at col. 5, lines 4-19 wherein the method of calculating risk, i.e. likelihood, of a person displaying genetic variability using the genetic variability of a general population is a known and practice method.

It would have been obvious to one of ordinary skill in the art to have used the method taught by Bowie of calculating risk when particular information was unavailable for use in the method taught by the combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN. This is because Hogan at paragraph [0037] teach that sometimes at the time of surgery genomic profiles are unavailable, but the information would still be helpful and effective to have. One of ordinary skill in the art would have recognized that applying the known method of method of calculating risk, i.e. likelihood,

of a person displaying genetic variability using the genetic variability of a general population in the method of customizing treatments based on risk as taught by the combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, and HOGAN would have yielded predictable results and resulted in an improved method. Furthermore, Hogan teaches decision trees based on available information with regards to determining the use of clinical agents based on hereditary information. Thus one of ordinary skill in the art would have immediately recognized that the method taught by Bowie would have been applicable in an analogous decision tree as encompassed by the instantly claimed method. This is because the differences between the claimed invention and the prior art were encompassed in known variation or in a principal known in the prior art.

The combination of REINHOFF, Fey et al., ICHIKAWA, EVANS, HOGAN and Bowie do not explicitly teach the limitation of a button, that when selected, directs the clinician to addition information regarding the association of the clinical agent and a genetic mutation linked to the polymorphism value.

Levine et al. teach an invention that is directed to the clinical management of chronic illness comprising GUIs that interface between clinician and patient. Levine et al. teach the commonly used functionality of adding buttons to GUIs throughout the Figures and throughout the reference, i.e. see paragraph [0099]. Levine et al. teach at paragraph [0116] the GUI comprising a link or interface widget, i.e. button, to associated information that is contextually relevant information, which may be displayed. Thus Levine et al. discloses the known practices of those skilled in the art of providing diverse functionalities of GUIs in a clinical setting.

It would have been obvious to one of ordinary skill in the art to have designed a GUI that comprised a button for a practitioner in order to pull up relevant or associated clinical information as taught by Levine et al. for use in the method taught by the combination of REINHOFF, ICHIKAWA, EVANS, and HOGAN and Bowie. This is because the combination of references teaches the manual procedure of looking up clinically relevant information such as information regarding an association of a clinical agent and a genetic mutation. The combination of references further teaches using computer systems and GUIs for use in clinical setting. Therefore, one of ordinary skill in the art could have applied the known method of adding buttons to GUIs as taught by Levine et al. in the same way to the already known manual procedure of seeking clinically relevant information and using GUIs and automated systems as also taught and the results would have been predictable to one of ordinary skill in the art.

Fey et al. does not explicitly teach automatically scheduling counseling for the person, automatically ordering follow-up tests, nor automatically providing a notification in an email address to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person's electronic medical record.

However, Fey et al. teach at paragraph [0042] generating custom reports of the genetic tests. Fey et al. further teach at paragraph [0044] the data is analyzed in conjunction with known medical data, such as disease, risk factors, screening factors, etc. Fey et al. at paragraph [0045] teach that the personalized health record reviews health risks and thoroughly explains test results with follow-up recommendations and determine further health risks.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have automated particular follow-up recommendations such as ordering another genetic test based on a health record or sending an email message to discontinue the administration of a particular drug with known adverse effects on the client with a particular genetic predisposition in the method of Ichikawa, Reinhoff, Evans, Fey and Hogan and Bowie. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result to a physician indicating an adverse effect of a particular drug being taken would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents as in claim 91.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have ascertained a low-risk or high-risk clinical response based on

whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents when generating the follow-up recommendations as taught by Fey et al.. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result ascertaining a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents, when generating the follow-up recommendations as taught by Fey et al. would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. teach at paragraphs [0019] and [0049] that the medical records are accessible and updating the healthcare system, wherein updating integrates heredity data with newfound knowledge as in claim 86 and 103.

With regards to claim 93, Hogan at paragraph [0187] teaches information generated by perioperative genomic profiling is automated. Hogan at paragraph [0187]

they teach a set of criteria to be met prior to administering a genetic test or genomic profile test, such as whether the subject is a candidate for genomic profiling, if a particular method is available for performing said test, if the method will provide useful information for a particular application and its practicality, and if there is clinical utility, i.e. provide a predication of a phenotype related to the genotype. Hogan at the background and paragraphs [0030] – [0034] discuss the cost-effectiveness and importance of it when performing perioperative testing of patients, i.e. genomic profiling. Furthermore, at paragraphs [0119] – [0127] Hogan teaches that only markers that correlate with a subject's response or ones that can provide effective and helpful information are included in obtaining a genomic profile. Hogan at paragraph [0031] – [0033] discusses a problem is "how to alter treatment course of action in response to results," as in genomic screening results and the present invention unites "medicine with genetics" to solve the described problem and to individualize treatment options for each subject. Thus, Ichikawa, Reinhoff, Evans, Fey, Hogan, and Bowie make the claimed invention obvious.

With regards to claim 104, the claim adds by way of limitation, the possibility of their being two demographic factors, for example, age and sex, etc. The added limitation of having an additional demographic factor does not alter or change the decision tree as recited in independent claim 94, but adds another demographic factor. The references above, i.e. Hogan, Bowie, etc. all disclose multiple factors in light of the disclosed decision trees as described above. For example, Bowie, discloses an individual's sex and age when describing calculating likelihoods as described above.

Therefore, the addition of another demographic factor as recited in claim 104, does not distinguish the claims over the prior art as the prior art looks at more than one demographic factor when performing the taught inventions and thus obviate the instant claims.

Response to Arguments

Applicant's arguments filed 8/18/2011 have been fully considered but they are not persuasive.

Applicant argues that the Bowie reference does not consider each and every element of steps (a) and (b) nor does not include logical steps which flow from one another that prefer using demographic information about the patient to determine genetic variability of the gene within the person.

Applicant's arguments are not found persuasive because Bowie describes that a health care practitioner or medical practitioner can calculate probability or likelihood of a genetic disorder using a variety of information ranging from the patient's own demographic information or from the general population which suggests the logical flow of the decision tree. However, the Bowie reference is viewed in light of the other references, i.e. Hogan, which further describes the logical flow from one to another, i.e. the decision tree as in the instant claims.

Applicant further argues that claim 104 has been added to expand upon the logical steps taken upon the invention.

Applicant's arguments are not found persuasive as the added claim merely adds the limitation of another general demographic factor wherein the references such as Bowie describe calculating likelihoods based on more than one demographic factor, such as age and sex.

Applicant argues that independent claim 91 being amended to clarify the method of determining whether to automatically generate a low-risk or high-risk clinical response has not been addressed by the rejection. In particular applicant argues that the reasoning for the Fey reference obviating the clarifying amendments is insufficient to render the specific test for selecting a high-risk and low-risk response obvious.

Applicant's arguments are not found persuasive as Fey is viewed in light of the other references it is combined for teaching the limitations of claim 91. With regards to automate a response, it was argued that the automation of manual procedures is not an unobvious limitation as described above. The Hogan reference in combination with the others clearly describe in adjusting responses in light of exposures based upon determined information, such as to anesthesia in emergency surgery situations, wherein a response can easily be distinguished between low and high risk. Therefore, it is found that in view of Fey and the other references that they do teach the decision tree and/or obviate its various forms.

Applicant further argues that once the determination has been made none of the references disclose carrying out the specific actions of reducing dosages to amounts below predetermined dangerous levels and placing an alternative order for an agent that is absent from the list of risk-associated agents or adding comments to an

electronic record indicating no risks were determined from the genetic test result value and outputting an interpretation at the GUI of the low risk clinical response.

Applicant's arguments are not found persuasive as the limitations have been addressed as described above wherein references disclose adjusting dosages based upon determined information and updating records that are output to healthcare or medical practitioners as described above.

Applicant further argues that the instant dual-response system based on the two criteria mentioned was not inherent but a new and advantageous way to use the results of the processes in claim 91.

Applicant's arguments are not found persuasive because it appears to be arguing unexpected results to support a case of non-obviousness or lack of inherency without providing any support or evidence. Absent further information, this appears to be opinion, which is not persuasive over the record.

Applciant argues that the tests for determining whether a low-risk or high-risk response is warranted is considerably different from Hogan's general statements above.

Applicant's arguments are not found persuasive as it was found that the responses described and taught by Hogan read on the instantly broad and reasonable interpretations of the instant claims.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /
Primary Examiner, Art Unit 1631